UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/739,451	12/17/2003	Dennis Rowe	03762.016200	9345

74432 7590 11/06/2009

Fitzpatrick Cella (Catalent)
1290 Avenue of the Americas
New York, NY 10104-3800

EXAMINER	
SAMALA, JAGADISHWAR RAO	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
11/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/739,451	ROWE ET AL.	
	Examiner	Art Unit	
	JAGADISHWAR R. SAMALA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-14 and 16-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-14 and 16-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Arguments and Remarks filed on 07/20/2009.

- Claim 1 has been cancelled.
- Claims 2-4 and 7 have been amended.
- Claims 2-14 and 16-18 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 rejected under 35 U.S.C. 112, second paragraph, **is withdrawn** in view of cancellation of the claim.

However, upon further consideration a new ground of rejection is made as follow.

Claims 2-14 and 16-18 are rejected under 35 U.S. C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially ungelatinized" in claim 2 is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary

skill in the art would not be reasonably apprised of the scope of the invention. It is not clear to what extent or percentage of starch is ungelatinized constitutes "substantially ungelatinized". Therefore, one would not know what the metes and bounds of the claims are.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 2-14 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borkan et al (US 4,935,243) in view of Lin et al (2003/0215495), Sano et al (US 6,280,767) and Stroud (5,554,385).

Applicant claims are drawn to a gelatin capsule comprising gelatin in about 20-55 weight%, plasticizer in about 19-40 weight %, hydroxypropylated starch in about 5-35

weight % a water content of 9.5-11.5 weight %; and capsule having a thickness not exceeding 0.030 inches .

Borkan et al. teach a chewable, edible soft gelatin capsule which comprises a shell comprising about 20-45% gelatin; about 17.5-35% plasticizer (which would read on glycerol); a hydrogenated starch hydrolysate effective to render said shell dispersible and soluble in the mouth of the user (see abstract and col. 2, lines 51-58). The gelatin include fish gelatin (type A) and bovine gelatin (type B) to obtain a gelatin with the requisite viscosity and bloom strength range from 6-300 (see col. 3 lines 30-45). The plasticizer includes glycerin, sorbitol or similar low molecular weight polyols (col.3, lines 48-56). Additional disclosure includes that the soft gel capsules are particularly effective for administration of medicines or other biologically-active substances to persons in medical distress, to elderly, to children, all of whom may not be able to swallow a hard capsule or chew a soft capsule for prolonged period. And this soft gelatin capsules allow these users to easily chew and ingest the active ingredients within the capsules in a palatable form.

Borkan fails to teach modified starch such as hydroxypropylated starch, water content of 9.5-11.5 weight % and capsule having a film thickness not exceeding 0.030 inches.

Lin teaches pharmaceutical composition comprising soft gelatin capsule (0072) comprising modified starch such as hydroxypropylated starch (0069), plasticizers such as glycerin, soribitol, polyethylene glycol (0047). Additional disclosure includes that the

soft gelatin capsules prepared have improved stability (active drug) under storage conditions without adversely affecting its bioavailability.

Sano teaches a chewable soft gelatin capsule comprising gelatin, one or more plasticizers such as sorbitol, glycerin, sucrose, mannitol and water soluble starch (abstract and col. 3 lines60). Sano teaches that after each capsule shell was filled with middle chain fatty acid triglyceride and molding was carried out, the capsule was dried, so that the water content of the capsule shell became 6-10 weight % to thereby obtain a soft gelatin capsule (col. 6 lines 18-26). Additional disclosure includes that by addition of increased amounts of plasticizers (starch) conventionally used for forming a gelatin shell and incorporating insoluble cellulose therein yields a soft gelatin capsule which has a soft, pleasant chewing texture and low stickiness and can be easily and reliable twisted open with the fingers.

Stroud teaches a soft gelatin capsule made by the rotary-die encapsulation process comprising gelatin, glycerol and modified starch. And gelatin capsules have wall thickness of about 0.030 inches (abstract and col. 3 lines 42-46).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate modified starch such as hydroxypropylated starch, water content of 9.5-11.5 weight % and capsule film having thickness of 0.030 inches into the soft gel capsules of Borkan. The person of ordinary skill in the art would have be motivated to make these modifications, because Lin teaches that that the composition (soft gel capsules) comprising plasticizer hydroxypropylated starch in combination with a solvent system comprising mixture of mono and diglycerides exhibit

unexpected and improved solubilization properties at ambient storage conditions over extended period of time without recrystallization and precipitation of loratadine, and thus hydroxypropylated starch permits high concentrations of solubilized drug per total fill volume and thereby permit the use of smaller capsules to deliver the same dosage of drug (abstract and 0072) and reasonably would have expected success because cited references are used in the same filed of endeavor such as capsule technology for drug delivery.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to incorporate water content of 9.5-11.5 weight % and capsule film having thickness of 0.030 inches into the soft gel capsules of Borkan. The person of ordinary skill in the art would have been motivated to do these modifications because Sano teaches that the soft gelatin capsules for chewing are easily broken in the mouth and exhibits low stickiness and excellent solubility. The person of ordinary skill in the art would have a reasonable expectation of success because Borkan and cited references teach composition comprising soft gelatin capsule that are used in the same field of endeavor such as soft gelatin capsules used for oral drug delivery systems, in food products and food additives.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It

would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as gelatin is a combination of fish and bovine gelatin and plasticizer for encapsulating pharmaceuticals, foods such as confections, and health foods and exhibit low stickiness and excellent solubility. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Conclusion

1. No claims are allowed at this time.

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618

sjr